fuse STERIZO™
TOTAL KNEE SYSTEM

INSTRUCTIONS FOR USE (IFU)

Fuse STERIZO Modular Knee System

Indications For Use:

The Fuse STERIZO Modular Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue in-balance. The tibial augments are to be attached to their respective components with a fixation screw or screws. The Fuse STERIZO Modular Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The Fuse STERIZO Modular Knee System is designed for cemented use only.

Contraindications Include:

Absolute contraindications include:

- Infection
- Sepsis
- Osteomyelitis
- Patients without sufficient bone stock to provide adequate fixation and/or support to the implant(s).

Relative contraindications include:

- An uncooperative patient or a patient with neurologic disorders who is incapable of following directions.
- Osteoporosis
- Metabolic disorders which may impair bone formation.
- Osteomalacia
- Distant foci of infections which may spread to the implant site.
- Rapid joint destruction marked bone loss or bone resorption apparent on roentgenogram.
- Vascular insufficiency, muscular atrophy, neuromuscular disease
- Incomplete or deficient soft tissue surrounding the knee
- Neuromuscular disorders affecting stability or postoperative complications.
- Weight, age, or activity levels that would put extreme loads on the implants causing premature wear and/or system failure

Materials:

The Fuse STERIZO Modular Knee Systems Tibial Tray consists of CoCrMo Alloy-ASTM F75. Tibial Augments, Offset Adapters and Stems consist of Titanium Alloy-ASTM F-136. PS+ Tibial insert consists of UHMWPE (Cross-Linked) ASTM F-2565. The Tibial Tray Plug consists of UHMWPE ASTM F-648.

Adverse Effects:

In all surgical procedures, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

- Material sensitivity reactions and the Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis, or osteolysis may be a result of loosening of the implant.
- Early or late postoperative infection and allergic reaction.
- Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
- Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption or excessive activity.
- Periarticular calcification or ossification, with or without impediment of joint mobility.
- Inadequate range of motion due to improper selection or positioning of components.
- Undesirable shortening of the limb.
- Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
- Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
- Wear and/or deformation of articulating surfaces.
- Valgus-varus deformity.
- Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
- Patellar tendon rupture and ligamentous laxity.
- Interoperative or postoperative bone fracture and/or postoperative pain.

Warnings & Precautions:

Improper selection, placement, positioning, alignment, and fixation of the implant components may result in unusual stress conditions, which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissues have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability. The Fuse STERIZO Modular Knee System provides the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal, healthy bone and joint tissue. Specialized instruments are designed for the Fuse

STERIZO Modular Knee System to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose.

MRI Safety Information:

The Fuse STERIZO Modular Knee System has not been evaluated for safety and compatibility in the MR environment. The Fuse STERIZO Modular Knee System has not been tested for heating or migration in the MR environment.

Postoperative Management:

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction, and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Sterilization:

For components provided Sterile, the sterilization method is noted on label. All prosthetic components, apart from tibial inserts, are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. All tibial inserts are sterilized by ethylene oxide.

WARNING: Please note that a single-use device (SUD) which encounters human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

WARNING: Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Retrieval and Analysis of Removed Implants:

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Fuse Medical customer service prior to the return of removed implants.

Symbol Glossary:

Symbol	Title/ Standard	Meaning
Rx Only	21 CFR 801.109b	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
REF	ISO 15223-1 5.1.6	Indicates the manufacturers catalogue number so that the medical device can be identified
LOT	ISO 15223-1 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1 5.1.4	Indicates the date after which the medical device is not to be used
QTY	Quantity	Indicates the quantity of devices
STERILE R	ISO 15223-1 5.2.4	Indicates a medical device has been sterilized using irradiation
STERILE EO	ISO 15223-1 5.2	Indicates a medical device has been sterilized using ethylene oxide
	ISO 15223-1 5.2	Indicates a medical device that is intended for one single use only
	ISO 15223-1 5.2.8	Indicates a product should not be used if the package is damaged or opened and the user should consult the instructions for use for additional information.
	ISO 15223-1 5.4.3	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
NON STERILE	ISO 15223-1 5.2.7	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 5.1.2	Indicates the medical device manufacturer
MD	ISO 15223-1	Indicates that the item is a medical device
UDI	ISO 15223-1 5.7.10	Indicates the manufacturer's batch code so that the batch or lot can be identified

Additional Information:

Comments, questions, or concerns regarding the use of this device should be directed to the following:

Website	www.FuseMedical.Com
Email	Info@FuseMedical.Com
Phone	469-862-3030
Postal	Attn: Customer Service CPM Medical Consultants, LLC 4343 Sigma Road, Suite 500 Farmers Branch, TX 75244
Website	www.FuseMedical.Com

Manufactured By:
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